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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,076	05/14/2001	Ian Jeffrey Evans	109846.205/SYN-071	2695

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SYNGENTA BIOTECHNOLOGY, INC.

PATENT DEPARTMENT

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,076

Applicant(s)

EVANS ET AL.

Examiner

Medina A Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 11, 13, 18-21 and 36-51 is/are pending in the application.
- 4a) Of the above claim(s) 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 11, 18-21 and 36-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 09-03.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 09/11/03 in reply to the Office action mailed 04/10/03 has been entered. Claims 4-10, 12, 14-17, and 22-23 have been cancelled. New claims 36-51 have been added. Therefore, claims 1-3, 11, 13, 18-21 and 36-51 are pending and are examined. Claim 13, depending upon cancelled claim 12, is labeled as "withdrawn", and therefore has not been further treated on the merits.

All previous rejections and objections not set forth below have been withdrawn.

The Declaration of Jason Vincent under 37 CFR 1.132 has been considered. The Declaration is persuasive with respect to the rejections under 35 USC 112, 1st paragraph. The Declaration is not persuasive regarding the art rejection.

Claim Rejections - 35 USC § 112

1. Claims 1-2, 18-21, 45-47 and 49-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the recitation of "when said linker peptide comprises a propeptide of an Ib-AMP precursor" in line 17 is inconsistent with the recitation "a linker propeptide comprising propeptide of an Ib-AMP precursor" in line 10. The latter implies the propeptide cannot be other than a propeptide of an Ib-AMP precursor. Dependent claims 2 and 18-21 do not obviate the rejection, and therefore,

are included in the rejection. It is suggested that "when said linker peptide comprises a propeptide of an Ib-AMP precursor" in line 17 be deleted.

Claim 45 and 49 are indefinite because the recitation of "when said linker peptide comprises SEQ ID NO: 3" in line 14 is inconsistent with the recitation, "a linker propeptide comprising propeptide of an Ib-AMP precursor " in line 7. The latter implies the propeptide cannot be other than SEQ ID NO: 3. Dependent claims 46-47 and 50-51 do not obviate the rejection, and therefore, are included in the rejection. It is suggested that "when said linker peptide comprises SEQ ID NO: 3" in line 14 be deleted.

Claim Rejections - 35 USC § 102

Claims 1-3, 11, 18- 21, and 36-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Attenborough et al (WO 95/24486, Applicant's IDS). This rejection is repeated for the reasons of record as set forth in the last Office action mailed 04/10/03. Applicant's arguments filed 09/11/03 have been considered but are not deemed persuasive.

Applicant argues that Attenborough does not disclose all limitations in claims 1, 3 or 48 (not 50)". Applicant asserts that the "at least one of said component protein molecules is expressed in said plant at higher level than in a plant transformed with a DNA sequence encoding that component molecule alone" and "wherein said linker propeptide provides a cleavage site whereby an expressed polypeptide is post-translationally processed into its component protein molecules in a secretory pathway of said plant" (response, pg 16-17) are not taught in the cited reference, and therefore, the

reference does not anticipate the claimed invention. Applicant urges that the rejection be withdrawn.

These arguments are not persuasive. In *Integra LifeScience I Ltd v. Merck KgaA (DC Scalif) 50 USPQ2d 1846 (2/9/1999)* at page 1848, the court stated " (w)hile every patent claim limitation must find a match, "[a]n anticipatory reference...need not duplicate word for word what is in the claims. Anticipation can occur when the claimed limitation is inherent or otherwise implicit in the relevant reference". MPEP 2112.02 on the other hand states " (w)hen the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process". Upon a closer reading of the teachings of Attenborough reference, it is noted that the cited reference teaches all limitations in the claims. In particular, at paragraph bridging pages 11 and 12, the reference teaches a method for expressing multiple proteins in a transgenic plant comprising inserting into the genome of the plant a plant expression vector comprising promoter sequence operably linked to a protein coding sequence of more than one protein, separated by a DNA sequence "which on translation provides a cleavage site whereby the expressed polyprotein is post-translationally processed into the component protein molecules". At page 12, the 1st full paragraph, the cited reference teaches seven Ib-AMP propeptide domains comprising five spacers (SEQ ID NO:14-18), one at the C-terminal (SEQ ID NO:20), and one N-terminus that is linked to a signal sequence (SEQ ID NO:21). See also page 29 for cleavage sites of different Ib-AMP propeptides. At pages 13-14, the reference teaches that any of said Ib-AMP propeptides can be comprised in the plant

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expression vector. The first full paragraph of page 14, the cited reference states, "(t)he protein components of the polyprotein may be identical, thus increasing expression of said protein... Alternatively, two or more different protein components may be linked in one polyprotein, enabling coordinated expression of the different proteins". The same paragraph also teaches that the Ib-AMO gene arrangement may be used with other antimicrobial peptides or proteins. The antimicrobial proteins Rs-AFP1 and Rs-AFP2 are disclosed at page 2, last full paragraph. At pages 30-32, the cited reference also teaches construction of plant expression vectors for polyproteins, and transformation of plants with said vectors (Examples 9-12). The cited reference teaches linker sequences (SEQ ID NO: 14-21) that fully anticipate the linker propeptides of the claimed methods. The DNA construct comprising a promoter operably linked to a multiple protein encoding sequences separated by any of the seven Ib-AMP propeptide linkers taught by Attenborough will inherently perform the claimed methods. Therefore, Attenborough discloses all claim limitations, as stated in the last Office action. The rejection is maintained.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

No claim is allowed.

Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

12/10/03

Mai


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER